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| 10/035,863 | 12/31/2001 | Bruce Robie | IMPLEX-13 | 4928 |
| 28581 | 7590 | 09/08/2005 | EXAMINER | |
| DUANE MORRIS LLP PO BOX 5203 PRINCETON, NJ 08543-5203 | | | PHILOGENE, PEDRO | |
| | | | ART UNIT | PAPER NUMBER |

3732

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,863

Applicant(s)

ROBIE ET AL.

Examiner

Pedro Philogene

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 15, 21, 22 and 25-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 15, 21, 22 and 25-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,15,25,29, 35, 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdizadeh (6,030,390) in view of Mikhail (5,308,350).

With respect to claims 1, 35, Mehdizadeh discloses an instrument system for preparing a disc space between adjacent vertebral bodies to receive a repair device, the instrument system comprising: at least one distractor (27) including a tapered body section (31) for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines; as set forth in column 3, lines 4-31; the tapered body section formed by an end wall, as best seen in FIGS.4,6,8, a first pair of opposing walls portions (32), as set forth in column 3, lines 19,20, converging toward the end wall; and a second pair of opposing wall portions (36) converging toward the end wall, as set forth in column 3, lines 20-30, and indicia; as set forth in column 5, line 25.

With respect to claims 15, 36, Mehdizadeh discloses a distractor for use in a system that prepares a disc space between adjacent vertebral bodies to receive a repair device, the distractor (27) comprising a tapered body section (31) for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines; as set forth in column 3, lines 4-31; the tapered body section formed by an end

Art Unit: 3732

wall a first pair of opposing walls portions (32) as set forth in column 3, lines 19-20 converging toward the end wall; and a second pair of opposing wall portions (36) converging toward the end wall, as set forth in column 3,, lines 20-30, and indicia, as set forth in column 5, line 25

It is noted that Mehdizadeh did not teach of connector section including a detent element, as claimed by applicant. However, in a similar art, Mikhail evidences the use of a securing means with a detent element to retain a connector end to coupling member.

Therefore, given the teaching of Mikhail, it would have been obvious to one having ordinary skill in the art, at the time the invention was made to modify the device of Mehdizadeh, as taught by Mikhail to retain connector section to the handle of the distractor.

With respect to claims 25,29, Mehdizadeh discloses all the limitations, as set forth, for example a connector section (29) for coupling a handle to the distractor, and a female coupling element (16).

Claims 21,22, 26-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehdizadeh (6,030,390) in view of Mikhail (5,308,350) in view of Burkus et al (6,648,895).

With respect to claims 21,22,26-34, it is noted that the above combination of references teaches all the limitations, except for a female coupling member formed by a T-Shape slot defining inwardly facing locking flanges; as claimed by applicant. However, in a similar art, Burkus et al evidences the use of a female coupling member formed by

Art Unit: 3732

a T-shape slot defining inwardly facing locking flange configured to receive the flange posts of the distractor and drive the distractor into the disc space.

Therefore, given the teaching of Burkus et al, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the female coupling member of the device of Mehdizadeh/Mikhail, as taught by Burkus et al to provide a device with a T-shape slot defining inwardly facing locking flange configured to receive the flange posts of the distractor and drive the distractor into the disc space.

As to the grooves on the pair of wall portions, as claimed by applicant; Burkus et al evidence that such a groove would have been obvious to engage the vertebral endplates and resist movement of distractor tip in the disc space.

Therefore, given the teaching of Burkus et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the pair of wall portions of Mehdizadeh/Mikhail, as taught by Burkus et al to provide a surface to engage the vertebral endplates and resist movement of the distractor tip in the disc space.

Response to Amendment

Applicant's arguments filed 8/12/05 have been fully considered but they are not persuasive. Applicant stated that "New claims 37-47 correspond to original claims 2-14, which were restricted out by the examiner as being "patentably distinct species", and were subsequently canceled. Claims 37-49 depend directly or indirectly from claim 1. Claim 1 is directed to an instrument system comprising at least one distractor. Claims 2-

Art Unit: 3732

14 recite additional elements of the instrument system. It is respectfully submitted that the instrument system of claim is generic, i.e., claim 1 includes no material element additional to those recited in the claims 2-14 or in other words, claims 2-14 contain all the limitations of claim 1. Therefore, upon allowance of claim 1, claims 37-49 should be considered and allowed.". However, since claim 1 is not being allowed and since claims 37-49 correspond to claims 2-14 which were restricted out, and were subsequently canceled, claims 37-49 would not be considered at this time.

Applicant's arguments with respect to claims 1, 15, 21, 22, 25-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

A shortened statutory period for reply to this action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3732

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene
September 01, 2005


PEDRO PHILOGENE
PRIMARY EXAMINER